## REMARKS/ARGUMENTS

This Response is being filed in conjunction with a Request for a continuing application under the provisions of 37 CFR § 1.114 and the appropriate fee. No new matter has been added. It is respectfully submitted that this Response addresses all of the issues raised by the Examiner in the above-identified Office Action and that the subject application now is in condition for allowance. Accordingly, reconsideration of the subject application is requested in view of the foregoing amendments and following remarks.

Turning first to the claim objections. The Examiner objected to Claim 23 as being grammatically incorrect due to the use of the word "and" instead of the word "an". By this amendment, dependent Claim 23 has been cancelled and its limitations incorporated into Claim 22 with the correct grammatical usage of the word "an" in the phrase "using an enzyme-linked" to overcome this objection.

Similarly, the Examiner object to Claim 27 for the redundant use of the word "in". By this amendment, Claim 27 has been amended to remove the word "in" so that the phrase "wherein said biological sample" now is grammatically correct and to overcome this objection.

Next, the Examiner rejected Claim 26 under 35 U.S.C. § 112 as lacking sufficient antecedent basis for the phrase "said animal" in Claim 25. By this amendment Claim 26 now correctly refers to the phrase "said mammal" in Claim 25, providing proper antecedent basis for Claim 26 and overcoming this rejection.

Turning now to the substantive rejection of the claims under 35 U.S.C. §§ 102(b) and 103(a), Applicants have amended the claims to more particularly point out and distinctly claim the features of the present invention which distinguish its methods from those of the art, particularly the art cited by the Examiner. As will be explained in detail, for these reasons, it is respectfully submitted that the remaining claims in this application, Claims 22, 24-27, contain allowable subject matter and notice to that effect is earnestly solicited.

More specifically, the Examiner has rejected Claims 22, 24-26 under 35 U.S.C. §102(b) as being unpatentably anticipated by the newly cited reference Wojtukiewicz et al. and as further evidenced by US Patent No 4,851,334. The Applicants respectfully traverse this rejection. It is specifically noted that Claim 23 was not rejected as being anticipated. Rather, Claim 23 was objected to for grammatical errors and subsequently rejected as being unpatentably obvious in view of these cited references. Accordingly, claim 23 has been cancelled by this amendment rendering the Examiner's objection to Claim 23 moot. Further, the limitations of canceled Claim 23 have been grammatically corrected and incorporated into independent Claim 22. Accordingly, for this reason alone, Claim 22 is not anticipated by the cited references and the remaining claims, Claims 24-27, which ultimately depend from Claim 22, are not anticipated as well. Further, none of these claims, as now amended, are anticipated by the cited references for the additional reason that the references do not disclose or suggest the present invention.

With respect to the teachings of the prior art, Applicants acknowledged in the Background of the Invention section of the subject application that many "cancer antigens" have been discovered and identified with polyclonal and monoclonal antibodies, including the commercially available monoclonal antibody T2G1. For example, as discussed in the Background of the subject application, as early as 1968 cancer associated markers provided evidence supporting the early concept that tumor cells of different lineages may release proteases into interstitial fluid and that increased protease activity may contribute directly to the invasiveness of tumor cells. Similarly, the 1996 Wojtukiewicz et al. reference cited by the Examiner also identifies the T2G1 monoclonal antibody in the context of the examination of the question of whether there is local thrombin generation and subsequent fibrin formation in gastric carcinoma tissue. Further, US Patent No. 4,851,334 cited by the Examiner, teaches that T2G1 is specific to peptide fragments of the f3-chain of human fibrinogen associated with the proteolysis of fibrin or fibrinogen.

In spite of these disclosures, none of the references discloses or suggests the present invention. Specifically, none of the cited references discloses or suggests that common oncogenic proteolytic processes may release universal markers or "pan-markers" that are not limited to a specific type of cancer but are associated with more universal oncogenic processes. Of equal importance, none of the cited references discloses or suggests that such markers can be screened for and identified as pan-markers suggesting the presence of more than one type of cancer in mammalian and human test subjects. Rather, the cited art references disclose and follow the generally accepted teachings of the art. In so doing, the cited references identify specific markers associated with specific cancers. These specific markers then can be utilized to identify the presence of the specific cancers as an aid in the further understanding of these specific disease conditions or as an aid in the effort to reduce the invasiveness or metastases of the specific cancers involved by downregulating the associated oncogenic mechanisms which generate the specific markers.

Nowhere, absent the hindsight teachings of the present invention, is there any disclosure or suggestion in the art of record to identify the association between a fibrinogen degradation product or products and common oncogenic processes that can provide a simple yet accurate screening process capable of detecting more than one type of cancer with a high degree of specificity and an acceptable degree of sensitivity. Independent Claim 22 has been amended to emphasize this novel and distinguishing aspect of the present invention and the Applicants respectfully request that this rejection under 35 U.S.C. § 102(b) be withdrawn.

In sum, the present invention is not the same as taught in the prior art and is not suggested by the prior art. Thus, the present invention is not anticipated by any of the cited references either alone or in combination. Claim 22 has been amended to emphasize this distinguishing aspect of the present invention and is in condition for allowance over the cited anticipatory references. As the remaining claims, Claims 24-27, ultimately depend from independent Claim 22, the foregoing arguments with respect

to Claim 22 are equally applicable to Claims 24-27 and these claims are allowable over the cited anticipatory references as well.

Turning next to the rejection of the claims under 35 U.S.C. § 103(a), the Examiner has rejected Claims 22-27 as being unpatentable over Wojtukiewicz et al. and US Patent No. 4,851,334. The Applicants respectfully traverse this rejection. As noted above, Claim 23 has been canceled, rendering its rejection moot. More importantly, the previous arguments relative to Wojtukiewicz et al. and US Patent No. 4,851,334 are equally appropriate to the patentability of remaining Claims 22, 24-27 under 35 U.S.C. §103(a). Neither of the cited references discloses or suggests the claimed invention. Regardless of the teachings of the cited references, as detailed by the Examiner in the above-identified Office Action, modulating the method disclosed in Wojtukiewicz et al. to include detection of specific FDP epitopes is not the present invention and does not lead one of ordinary skill in the art to the present invention. In contrast to the teachings and suggestions of these references, either alone or in combination, the present invention utilizes the primary step of identifying the association or correlation between fibrinogen degradation products and common oncogenic proteolytic processes indicative of the presence of a variety of cancers, not just gastric cancer, in the target mammalian or human subjects. Identifying this association, an association that is absent in the prior art, is part of the present invention methods of screening for more than one type of cancer with a high degree of specificity and an acceptable degree of sensitivity. This association is not disclosed or suggested in the cited references. Accordingly, the present invention is not obvious in view of the cited references and this rejection of Claims 22, 24-27, as now amended, should be withdrawn. Remaining Claims 22, 24-27 are allowable and notice to that effect is respectfully requested.

The Applicants have amended the pending claims of the subject application to address the Examiner' s objections and rejections and to place the remaining claims in condition for allowance. Further, the Applicants have presented arguments demonstrating the patentable novelty and non-obviousness of the amended claims over the recently cited references. Therefore, the Applicants respectfully assert that the

claims contain allowable subject matter and request that the rejections and objections be withdrawn and that the Examiner allow the presently pending claims. If the Examiner believes that a telephonic interview with the Applicants or the Applicants' attorney will advance the allowance of this case, the Examiner is requested to contact the undersigned at the telephone number provided below.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 50-1329.

Respectfully submitted,

Dated: 1/9/04

Louis C. Cullman
Registration No. 39,645
CUSTOMER NUMBER: 31,278

STRADLING YOCCA CARLSON & RAUTH
660 Newport Center Drive, Suite 1600
Newport Beach, CA 92660
Telephone: (949) 725-4000
Facsimile: (949) 725-4100